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ABBOTT CARDIOVASCULAR SYSTEMS INC./ FINNEGAN HENDERSON L.L.P. 901 NEW YORK AVENUE, N.W. WASHINGTON, DC 20001			FOREMAN, JONATHAN M	
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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* WAYNE E. CORNISH and SHARON WONG

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Appeal 2010-001944  
Application 09/746,144  
Technology Center 3700

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Before: STEVEN D. A. MCCARTHY, KEN B. BARRETT, and  
PHILLIP J. KAUFFMAN, *Administrative Patent Judges*.

KAUFFMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

## STATEMENT OF CASE

Appellants appeal under 35 U.S.C. § 134 from a rejection of claims 7 and 20-26. The Examiner rejects claims 7 and 20-26 under 35 U.S.C. § 103(a) as being unpatentable over Anderson (US 6,325,766 B1; issued December 4, 2001) and Stevens (US 5,722,981; issued March 3, 1998); and claims 7 and 22-26<sup>1</sup> under 35 U.S.C. § 103(a) as being unpatentable over Yamauchi<sup>2</sup> (JP H 4-187159 A; published July 3, 1992) and Abel (US 6,428,317 B1; issued August 6, 2002). We have jurisdiction under 35 U.S.C. § 6(b).

We reverse.

## THE INVENTION

Appellants' claimed invention relates to an elongated guiding member for a medical procedure. Spec. 1:5. Independent claim 7, reproduced below, is representative of the claimed subject matter:

7. An elongated device for medical procedures comprising a superelastic member having a first section with a first set of properties and an adjacent second section having a second set of properties which have been altered from the first set of properties by treating the second section with an easily diffusible element,

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<sup>1</sup> As identified in the Office Action that is the subject of this appeal, the adverse decision of the Examiner before us is the rejection of claims 7 and 22-26 as unpatentable over Yamauchi and Abel. Office Action dated May 30, 2008, p. 3. In contrast, the Examiner's Answer identifies claims 7 and 21-25 (*vice* 22-26); however, this appears to be incorrect because it is not a new ground of rejection (it is not identified as a new ground of rejection, nor signed by a Technology Center Director or designee). *See* Ans. *passim*; *see also* Reply Br. 3 (noting this change from the Office Action to the Answer).

<sup>2</sup> All citations to Yamauchi refer to the Official English Translation of Yamauchi, translated by FLS, Inc., June 2009, PTO 09-6340.

wherein said easily diffusible element is selected from the group consisting of oxygen, hydrogen, and nitrogen, and the superelastic member comprises a nickel-titanium alloy.

## ISSUES

The issues present by this appeal are:

Has the Examiner articulated an adequate reason based on a rational underpinning to explain why a person of ordinary skill in the art would have been led to form the second section of Anderson's elongated device of a nickel-titanium alloy that includes oxygen or hydrogen, as taught by Stevens, to reach the subject matter of independent claim 7?

Would a person of ordinary skill in the art have found the subject matter of claim 7 obvious in view of Yamauchi and Abel?

## ANALYSIS

*Rejection of claims 7 and 20-26 under 35 U.S.C. § 103(a) as being unpatentable over Anderson and Stevens*

Independent claim 7 calls for the second section of the nickel-titanium alloy superelastic member to have properties different from that of the first section by treating the second section with an easily diffusible element selected from the group consisting of oxygen, hydrogen, and nitrogen.

The Examiner found that Anderson discloses an elongated device comprised of a superelastic member as called for in independent claim 7, except that Anderson's second section is not treated with an easily diffusible element selected from the group consisting of oxygen, hydrogen, and nitrogen. Ans. 3-4. The Examiner found that Stevens discloses a nickel-titanium alloy that includes oxygen or hydrogen. Ans. 4. The Examiner concluded that it would have been obvious to substitute a nickel-titanium

alloy that has been treated with oxygen or hydrogen as taught by Stevens for the material used to form the second section of Anderson's elongated device, in order "to achieve the predictable results of allowing the medical device to have a pre-formed shape, be stressed into another shape, and then return to its pre-formed shape." *Id.*

Anderson discloses that the second section of the elongated device (proximal portion 12) requires high torquability and sufficient column strength to be pushed through a patient's vascular system without kinking and consequently should be formed of substantially nickel-free high-nitrogen austentic stainless steel alloy in order to have improved tensile and fatigue strength compared to conventional nickel-containing alloys.

Anderson, col. 1, ll. 22-26, 42-46; col. 2, ll. 14-17; fig. 1. While Anderson discloses that other "suitable" and "conventional" materials may be used to form the second section of the elongated device (proximal portion 12), the other materials specified are not superelastic. Anderson, col. 2, ll. 49-62.

The Examiner proposes to modify the second section of Anderson's elongated device (proximal portion 12) to add the very element (nickel) that Anderson discloses should not be used to form that section, suggesting such a modification would not have been obvious. *See In re Haruna*, 249 F.3d 1327, 1335 (Fed. Cir. 2001) ("A reference may be said to teach away when a person of ordinary skill, upon reading the reference, . . . would be led in a direction divergent from the path that was taken by the applicant." (citation omitted)); *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007) ("[W]hen the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious.").

Further, the Examiner's rationale does not otherwise explain why a person of ordinary skill in the art would make such a modification.

Stevens discloses a medical device 70 for closing surgical wounds, having a suture engaging loop 96 formed of shape memory alloy (SMA), such as a nickel-titanium alloy that contains hydrogen and oxygen, which can be contorted out of a "pre-formed" shape when a force is applied, and will return to its "pre-formed" shape after that force is removed. Stevens, col. 1, ll. 11-12; col. 3, ll. 19-20, 36, 41-52. Such characteristics are desirable in the first section (distal portion 14) of Anderson's elongated device, which is formed from pseudo- or super-elastic alloys and shape memory alloys such as nickel-titanium alloys, in order to be flexible enough to select the branch of vasculature desired and avoid damaging the blood vessel or other body lumen the device passes through. Anderson, col. 1, ll. 29-32; col. 2, ll. 39-43; fig. 1. However, the second section (proximal portion 12) of Anderson's elongated device is not described as requiring such characteristics. Rather, Anderson's second section (proximal portion 12) is described as requiring high torquability and sufficient column strength to be pushed through a patient's vascular system without kinking. Anderson, col. 1, ll. 22-26, 42-46; col. 2, ll. 14-17; fig. 1.

A person of ordinary skill in the art would recognize that the second section (proximal portion 12) of Anderson's elongated device has no need of the characteristics of a nickel-titanium shape memory that contains hydrogen and oxygen as disclosed by Stevens.

Given this, the modification proposed by the Examiner would add the very element Anderson discloses should not be used, only to provide characteristics that the second section (proximal portion 12) of Anderson's elongated device does not need. Consequently, we agree with Appellants

that the rationale provided does not sufficiently account for why a person of ordinary skill in the art would have made the proposed modification. See App Br. 12-13; Reply Br. 6-8. As such, we reverse the rejection of independent claim 7, and its dependent claims 20-26.

*Rejection of claims 7 and 22-26 under 35 U.S.C. § 103(a) as being unpatentable over Yamauchi and Abel*

The Examiner found that Yamauchi discloses an elongated member as called for in independent claim 7, except that Yamauchi's second section (core 2) has been treated with carbon rather than an element selected from the group of oxygen, hydrogen, and nitrogen. Ans. 4-6. The Examiner found that Abel discloses the addition of oxygen and nitrogen to nickel-titanium alloys. Ans. 4. The Examiner found Appellants' previous inclusion of carbon as a member of the group of easily diffusible elements is evidence that carbon is equivalent to oxygen, hydrogen, or nitrogen.<sup>3</sup> Ans. 6. The Examiner concluded it would have been obvious to modify the second section (core 2) of Yamauchi's superelastic member using Abel's technique of treating the alloy with oxygen or nitrogen, "in order to allow a portion the core to exhibit enhanced superelastic properties." Ans. 5.

This rejection relies upon Appellants' disclosure as evidence of the equivalency of carbon to a member of the group consisting of oxygen, hydrogen, or nitrogen. Such evidence must be found in the prior art, and cannot be based on Appellant's own disclosure (unless that disclosure admits that the equivalence was known in the art). *In re Ruff*, 256 F.2d 590, 596-98 (CCPA 1958). Thus, we look to the prior art for such evidence.

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<sup>3</sup> See e.g., original claim 10 submitted December 21, 2000.

Yamauchi discloses a superelastic member having a second section (core 2) that is a titanium-nickel alloy that includes carbon. Yamauchi, p. 2, ll. 7-8. However, contrary to the Examiner's finding, Yamauchi does not disclose that carbon is an easily diffusible element. See Ans. 6 (citing Yamauchi p. 4, ll. 12-15). The portion of Yamauchi relied upon discloses that, "the inventors found that even if TiNi [titanium and nickel] alloy had C [carbon] added to it, the essential TiNi alloy properties are not damaged and it is useful in improving the shape-memorizing properties, particularly the reversible shape-memorizing effect." Thus, Yamauchi discloses the effects of the addition of carbon to a nickel-titanium alloy. However, this portion of Yamauchi does not disclose that carbon is easily diffused in nickel-titanium alloys. Further, the Examiner has not pointed to, nor can we find, any disclosure in Abel that carbon is easily diffused in nickel-titanium alloys.

Abel discloses that the addition of trace elements such as oxygen and nitrogen can have very significant effects on desired superelastic properties and performance of titanium and nickel alloys used to form endodontic files. Abel, col. 3, l. 65-67; col. 4, l. 7-12. However, Abel does not disclose that carbon is equivalent to oxygen, hydrogen, or nitrogen when diffused in nickel-titanium alloys. Further, the Examiner has not pointed to, nor can we find, that Yamauchi discloses such equivalence.

We agree with Appellants that neither reference discloses that carbon is an easily diffusible element, and that neither reference discloses the equivalence of carbon and an element selected from the group of oxygen, hydrogen, or nitrogen when diffused in nickel-titanium alloys. See App. Br. 15-17; Reply Br. 9-13. The Examiner has not set forth findings and analysis sufficient to establish an apparent reason to modify the second section of Yamauchi's superelastic member, which is formed of a nickel-titanium alloy

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containing carbon, to instead be formed of a nickel-titanium alloy that includes an element from the group consisting of oxygen, hydrogen, or nitrogen, as taught by Abel, to arrive at the subject matter called for in claim 7. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (a conclusion of obviousness must be supported by explicit findings and analysis establishing an apparent reason to combine the known elements in the manner required in the claim at issue).

As such, we cannot sustain the rejection of independent claim 7 or its dependent claims 22-26.

## CONCLUSIONS

The Examiner has not articulated an adequate reason based on a rational underpinning to explain why a person of ordinary skill in the art would have been led to form the second section of Anderson's elongated device of a nickel-titanium alloy that includes oxygen or hydrogen, as taught by Stevens, to reach the subject matter of independent claim 7.

A person of ordinary skill in the art would not have found the subject matter of claim 7 obvious in view of Yamauchi and Abel.

## DECISION

We reverse the Examiner's decision to reject 7 and 20-26 under 35 U.S.C. § 103(a) as being unpatentable over Anderson and Stevens.

We reverse the Examiner's decision to reject 7 and 22-26 under 35 U.S.C. § 103(a) as being unpatentable over Yamauchi and Abel.

## REVERSED

mls/nlk